DEPARTMENT OF HEALTH & HUMAN SERVICES

New York District

Food & Drug Administration
300 Pearl Street, Suite 100
Buffalo, NY 14202

May 20, 1999

WARNING LETTER NYK 1999-45

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

Stephen E. Haines, Owner
Haines Farms
156 McLean Road
Cortland, NY 13045

Dear Mr. Haines,

An investigation performed by U.S. Food and Drug Administration Investigator David M. McNew included an inspection of your dairy farm performed March 23-24 & 26, 1999. The investigation confirmed you offered an animal for sale for slaughter as food in violation of Sections 402(a)(2)(C)(ii) and 402(a)(4) of the Federal Food, Drug, and Cosmetic Act (the Act), and that you may have caused animal drugs to become adulterated within the meaning of Section 501(a)(5).

On or about December 7, 1998, you sold a cow that had been assigned barn tag number 8, and metal ear tag number 21ZAD1345, to [redacted], for slaughter for human food. The cow was subsequently slaughtered on 12/8/98 at [redacted] USDA analysis of tissue samples collected from that animal identified the presence of 1.3 ppm gentamicin in the kidney. There is no permitted level for residues of gentamicin in edible tissues of cattle. The presence of this drug in kidney tissue of this animal causes the food to be adulterated within the meaning of Section 402(a)(2)(C)(ii).

Our investigation also found you hold animals under conditions which are so inadequate that diseased animals and/or medicated animals bearing potentially harmful drug residues are likely to enter the food supply. For example, you lack an adequate system for assuring that animals have been treated only with drugs which have been approved for use in those species; for assuring that drugs are used in a manner not contrary to the directions contained in the labeling; and for assuring that animals medicated by you have been withheld from slaughter for appropriate periods of time to permit depletion of potentially hazardous residues of drugs from edible tissues. Foods from animals held under such conditions are adulterated within the meaning of Section 402(a)(4) of the Act.

You are adulterating the drug [redacted] brand [redacted] containing gentomycin sulfate and dexamethasone, used at your farm to treat mastitis in dairy cattle. The drug is adulterated within the meaning of Section 501(a)(5) of the Act when you fail to use it in conformance with its approved labeling. Your use of this drug without following the labeled withdrawal period causes it to be unsafe for use.

You should take prompt action to correct the above violations and to establish procedures whereby such violations do not recur. Failure to do so may result in regulatory action without further notice. This may include seizure or injunction.

It is not necessary for you to personally ship an adulterated animal in interstate commerce to be responsible for a violation of the Federal Food, Drug and Cosmetic Act. The fact that you caused the adulteration of an animal that was sold and subsequently offered for sale to a slaughterhouse that ships in interstate commerce is sufficient to hold you responsible for a violation of the Act.

Please notify this office in writing, within 15 days, of the steps you have taken to prevent a recurrence of similar violations. Your response should be directed to James M. Kewley, Compliance Officer, at the above address.

Sincerely,

Brenda J. Holman
District Director

cc: Benjamin F. Turner, DVM., Partner
Midstate Veterinary Services
987 Route 222
Cortland, NY 13045

cc: Paul B. Coen, DVM, Partner
Midstate Veterinary Services
987 Route 222
Cortland, NY 13045

cc: Michael Griep, DVM, Partner
Midstate Veterinary Services
987 Route 222
Cortland, NY 13045